

### Objections

The Examiner objects to claims 2, 5, 7, 8, and 10 as being dependent upon a rejected base claim. As shown below, claim 1, from which claims 2, 5, 7, 8, and 10 ultimately depend, is allowable. Thus, the objections to claims 2, 5, 7, 8, and 10 are moot.

Applicant requests reconsideration and withdrawal of the objections.

### Rejections Under 35 U.S.C. § 103(a)

The Examiner rejects claims 1, 3, 4, 6, 9, and 11-13 under 35 U.S.C. §103(a) as allegedly obvious over Sharma et al., *Atherosclerosis*, 33:371-375 (1979) ("Sharma"), in view of McCoy et al., U.S. Pat. No. 4,379,177 ("McCoy"). Specifically, the Examiner alleges that "Sharma teaches the administration of isoflavone compositions comprising biochanin A, formononetin, and pratensein obtained from commonly used legumes [soy] for lowering levels of serum cholesterol and triglycerides in rats." Office Action, page 4, lines 7-9.

The actual experiment described by Sharma examined various single isoflavones administered by gastric intubation. The test rats were starved for 24 hours and then subjected to hyperlipidemia induced by intraperitoneal injection of Triton-WR1339, followed by 43 hours of starvation. Immediately after Triton injection and twenty hours later, the test rats received doses of a single purified isoflavone administered by gastric intubation.

McCoy describes a stable dehydrated cocrystalline amino acid food additives. Specifically, McCoy states that undesirable off flavors of free amino acids in food can be reduced or eliminated by mixing amino acids with a cocrystallize material followed by dehydration. See McCoy, Col. 3, lines 3-13, and 35-38, and Col. 4, lines 15-21.

Claim 1 of the application is directed to a method for treating or reducing predisposition to a number of conditions, including elevated blood cholesterol, by administering a health

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com

supplement comprising two or more phyto-estrogens extracted from soya or clover. The phyto-estrogens are from the group genistein, daidzein, biochanin A, formononetin, or the natural glycosides of any of the phyto-estrogens. Claims 3, 4, 6, and 9 ultimately depend from claim 1.

A reference must suggest the desirability of the claimed invention, and suggest the motivation to modify of the reference. Manual of Patent Examining Procedure ("MPEP") §2143.01. Sharma does not suggest methods for treating or reducing the predisposition to elevated blood cholesterol by administration of a therapeutically effective amount of a health supplement composition comprising any two or more phyto-estrogens of the group genistein, daidzein, biochanin A, formononetin, or the natural glycosides of any of these phyto-estrogens.

Specifically, Sharma does not suggest the use of a health supplement comprising two or more of the enumerated phyto-estrogens. Sharma merely describes the use of single purified isoflavones administered by gastric intubation.

Further, Sharma does not suggest methods for treating or reducing the predisposition to elevated blood cholesterol by administration of a therapeutically effective amount of a health supplement. Sharma merely shows the effects of individual isoflavones on Triton-WR1339 induced hyperlipodemic starved rats. One of skill in the art would see Sharma as merely a preliminary study, confined to experimentally induced hyperlipidemia in rats, and the administration of single purified isoflavones by gastric intubation. Applicant believes that it is unreasonable to infer that a lowering of cholesterol levels in starved rats with chemically induced hyperlipidemia can be regarded as teaching any health benefits with respect to individual isoflavone compounds.

McCoy does not remedy the deficiencies of Sharma. McCoy does not suggest the use of health supplements comprising two or more phytoestrogens. Further, McCoy does not suggest

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com

methods for treating or reducing the predisposition to elevated blood cholesterol or any of the other conditions recited in claim 1.

For at least the reasons stated, claim 1 is not rendered obvious by Sharma in view of McCoy. As claims 3, 4, 6, and 9 ultimately depend from claim 1, claims 3, 4, 6, and 9 are not rendered obvious by Sharma in view of McCoy.

Claim 11 is directed to a pharmaceutical preparation, in solid dosage unit form, in which the biologically active component comprises any two or more concentrated, phytoestrogen-derived isoflavones selected from the group consisting of genistein, daidzein, biochanin A, formononetin or the natural glycosides of any of these phytoestrogens. The claimed preparation also includes a pharmaceutically acceptable carrier. Claims 12 and 13 ultimately depend from claim 11.

Not only does Sharma not suggest a pharmaceutical preparation comprising any two or more of concentrated phytoestrogen-derived isoflavones selected from the group comprising genistein, daidzein, biochanin A, formononetin, or the natural glycosides of any of these phytoestrogens, Sharma does not suggest a preparation including a pharmaceutically acceptable carrier. Sharma only recites the use of a single purified isoflavone suspended in aqueous methylcellulose to be used in gastric intubation. Thus, Sharma does not suggest a pharmaceutical preparation, nor does Sharma suggest the use of two or more of the enumerated isoflavones. Finally, Sharma does not suggest the use of a pharmaceutically acceptable carrier.

McCoy does not remedy the deficiencies of Sharma. For example, nowhere does McCoy suggest the use of two or more of the enumerated isoflavones or the use of a pharmaceutically acceptable carrier.

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com

Further, there must be some suggestion or motivation to combine the references. The mere fact that references can be combined is not sufficient to establish prima facie obviousness. MPEP §2143.01 and §2145 X.C. The Examiner has not shown any motivation to combine the references of Sharma and McCoy.

Thus, for at least the reasons stated above, claim 11 is not obvious over Sharma in view of McCoy. Claims 12 and 13 ultimately depend from claim 11, and for at least the reasons stated above, are also not obvious over Sharma in view of McCoy. Accordingly, Applicant respectfully requests reconsideration and withdrawal of all rejections under 35 U.S.C. §103(a).

Conclusion

Applicant respectfully requests reconsideration withdrawal of all rejections. Further, Applicant requests the timely and expeditious allowance of all pending claims.

Please charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: February 5, 2003

By: 

Robert W. Mann  
Reg. No. 48,555

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com